

What is claimed is:

- 1        1. A system for diagnosing and monitoring outcomes of atrial  
2        fibrillation for remote patient care, comprising:
  - 3              a database storing a plurality of monitoring sets which each comprise  
4              recorded measures relating to patient information recorded on a substantially  
5              continuous basis;
  - 6              a server retrieving and processing a plurality of the monitoring sets,  
7              comprising:
    - 8                  a comparison module receiving a diagnosis of atrial fibrillation and  
9                  determining at least one patient status change in response to the atrial fibrillation  
10               diagnosis by comparing on a periodic basis at least one recorded measure from  
11               each of the monitoring sets to at least one other recorded measure from another of  
12               the monitoring sets with both recorded measures relating to a same type of patient  
13               information; and
    - 14                  an analysis module evaluating on a periodic basis each patient  
15               status change for an absence, an onset, a progression, a regression, and a status  
16               quo of atrial fibrillation against a predetermined indicator threshold corresponding  
17               to the same type of patient information as the recorded measures which were  
18               compared, the indicator threshold corresponding to a quantifiable physiological  
19               measure of a pathophysiological diagnosis resulting from atrial fibrillation.
- 1        2. A system according to Claim 1, further comprising:
  - 2              an analysis submodule managing the atrial fibrillation diagnosis by  
3              controlling at least one of a ventricular rate response control unit and a normal  
4              sinus rhythm restoration unit.
- 1        3. A system according to Claim 1, further comprising:
  - 2              at least one of a medical device adapted to be implanted in an individual  
3              patient and an external medical device proximal to the individual patient;
  - 4              a database submodule periodically receiving the monitoring set for an  
5              individual patient, with each recorded measure in the monitoring set recorded by

6 the at least one of a medical device adapted to be implanted and the external  
7 medical device and storing the received monitoring set in the database as part of a  
8 patient care record for the individual patient.

1           4. A system according to Claim 3, further comprising:  
2           a set of further indicator thresholds, each indicator threshold  
3 corresponding to a quantifiable physiological measure used to detect a  
4 pathophysiology indicative of diseases other than atrial fibrillation;  
5           a comparison submodule comparing each patient status change to each  
6 such further indicator threshold corresponding to the same type of patient  
7 information as the at least one recorded measure and the at least one other  
8 recorded measure from another of the monitoring sets and testing each patient  
9 status change against each such further indicator threshold corresponding to the  
10 same type of patient information as the recorded measures which were compared.

1           5. A system according to Claim 1, wherein the recorded measures  
2 comprise quality of life measures, further comprising:  
3           a comparison submodule determining a change in patient status by  
4 comparing at least one such recorded quality of life measure to at least one other  
5 such corresponding recorded quality of life measure.

1           6. A system according to Claim 1, further comprising:  
2           a set of stickiness indicators for each type of patient information, each  
3 stickiness indicator corresponding to a temporal limit related to a program of  
4 patient diagnosis or treatment;  
5           a comparison submodule measuring a time occurring between each patient  
6 status change for each recorded measure to the stickiness indicator relating to the  
7 same type of patient information as the recorded measure being compared; and  
8           an analysis submodule determining a revised program of patient diagnosis  
9 or treatment responsive to each patient status change occurring subsequent to the  
10 time following the stickiness indicator.

1           7. A system according to Claim 1, further comprising:

2           a database submodule module retrieving the plurality of monitoring sets  
3 from a patient care record for one of an individual patient, a peer group, and an  
4 overall patient population.

1           8.       A system according to Claim 1, further comprising:  
2           the database further storing a reference baseline comprising recorded  
3 measures which each relate to patient information recorded during an initial time  
4 period and comprise either medical device measures or derived measures; and  
5           a database submodule obtaining at least one of the at least one recorded  
6 measure and the at least one other recorded measure from the reference baseline.

1           9.       A system according to Claim 1, wherein the indicator threshold  
2 relates to at least one of a finding of reduced exercise capacity, respiratory  
3 distress, palpitations or symptoms.

1           10.      A system according to Claim 9, wherein the indicator thresholds  
2 relating to the finding of reduced exercise capacity are selected from the group  
3 consisting of decreased cardiac output, decreased mixed venous oxygen score and  
4 decreased patient activity score.

1           11.      A system according to Claim 9, wherein the indicator thresholds  
2 relating to the finding of respiratory distress are selected from the group  
3 consisting of increased pulmonary artery diastolic pressure, increased respiratory  
4 rate and decreased transthoracic impedance.

1           12.      An automated collection and analysis patient care system for  
2 diagnosing and monitoring outcomes of atrial fibrillation for remote patient care,  
3 comprising:

4           a database storing patient monitoring information, comprising:  
5            a plurality of monitoring sets, each monitoring set comprising  
6 recorded measures which each relate to patient information and comprise either  
7 medical device measures or derived measures, the medical device measures  
8 having been recorded on a substantially continuous basis;

9                   a set of stored indicator thresholds, each indicator threshold  
10          corresponding to a quantifiable physiological measure of a pathophysiological  
11          diagnosis resulting from atrial fibrillation and relating to the same type of patient  
12          information as at least one of the recorded measures;

13                   a server diagnosing an atrial fibrillation finding, comprising:

14                   an analysis module receiving a diagnosis of atrial fibrillation and  
15          determining on a periodic basis a change in patient status in response to the atrial  
16          fibrillation diagnosis by comparing at least one recorded measure to at least one  
17          other recorded measure from another of the monitoring sets with both recorded  
18          measures relating to the same type of patient information; and

19                   a comparison module comparing on a periodic basis each patient  
20          status change for an absence, an onset, a progression, a regression, and a status  
21          quo of atrial fibrillation to the stored indicator threshold corresponding to the  
22          same type of patient information as the recorded measures which were compared.

1                 13.    A system according to Claim 12, wherein the device measures are  
2          recorded by at least one of a medical device adapted to be implanted in an  
3          individual patient and an external medical device proximal to the individual  
4          patient when the device measures are recorded.

1                 14.    A system according to Claim 12, wherein each of the monitoring  
2          sets comprises recorded measures relating to patient information solely for the  
3          individual patient, further comprising:

4                   a database module retrieving each monitoring set from a patient care  
5          record for an individual patient and obtaining the at least one recorded measure  
6          and the at least one other recorded measure from the retrieved monitoring sets.

1                 15.    A system according to Claim 12, wherein each of the monitoring  
2          sets comprises recorded measures relating to patient information for a peer group  
3          of patients to which the individual patient belongs, further comprising:

4                   a database module retrieving at least one monitoring set from a patient  
5          care record for the individual patient, retrieving at least one other monitoring set

6 from a patient care record in the same patient peer group, and obtaining the at  
7 least one recorded measure from the at least one monitoring set and the at least  
8 one other recorded measure from the at least one other monitoring set.

1           16. A system according to Claim 12, wherein each of the monitoring  
2 sets comprises recorded measures relating to patient information for a population  
3 of patients, further comprising:

4           a database module retrieving at least one monitoring set from a patient  
5 care record for the individual patient, retrieving at least one other monitoring set  
6 from a patient care record in the patient population, and obtaining the at least one  
7 recorded measure from the at least one monitoring set and the at least one other  
8 recorded measure from the at least one other monitoring set.

1           17. A system according to Claim 12, further comprising:  
2           a medical device adapted to be implanted;  
3           the database further storing a reference baseline comprising recorded  
4 measures which each relate to patient information recorded by the medical device  
5 during an initial time period and comprise either device measures recorded by the  
6 medical device adapted to be implanted or derived measures; and  
7           a database module obtaining at least one of the at least one recorded  
8 measure and the at least one other recorded measure from the retrieved reference  
9 baseline.

1           18. A system according to Claim 12, wherein the reference baseline  
2 comprises recorded measures relating to patient information for one of the  
3 individual patients solely, a peer group of patients to which the individual patient  
4 belongs, and a general population of patients.

1           19. A system according to Claim 12, the comparison module further  
2 comprising:  
3           a module grading the comparisons between each patient status change and  
4 corresponding stored indicator threshold on a fixed scale based on a degree of  
5 deviation from the stored indicator threshold; and

6           the comparison module determining an overall patient status change by  
7   performing a summation over the individual graded comparisons.

1           20.     A system according to Claim 12, the comparison module further  
2   comprising:

3               a module determining probabilistic weightings of the comparisons  
4   between each patient status change and corresponding stored indicator threshold  
5   based on a statistical deviation and trends via linear fits from the stored indicator  
6   threshold; and

7               the comparison module determining an overall patient status change by  
8   performing a summation over the individual graded comparisons.

1           21.     A system according to Claim 12, the server further comprising:  
2               a feedback module recording quality of life and symptom measures into  
3   each monitoring set;

4               a quality of life module determining a change in patient status by  
5   comparing at least one recorded quality of life measure to at least one other  
6   corresponding recorded quality of life measure; and

7               the server incorporating each patient status change in quality of life into  
8   the atrial fibrillation finding to either refute or support the diagnosis.

1           22.     A system according to Claim 12, further comprising:  
2               a set of stored further indicator thresholds, each stored further indicator  
3   threshold corresponding to a quantifiable physiological measure used to detect a  
4   pathophysiology indicative of diseases other than atrial fibrillation; and

5               the server diagnosing a finding of a disease other than atrial fibrillation,  
6   the comparison module further comparing each patient status change to each such  
7   further indicator threshold corresponding to the same type of patient information  
8   as the at least one recorded measure and the at least one other recorded measure.

1           23.     A system according to Claim 12, further comprising:  
2               a set of stickiness indicators, each stickiness indicator corresponding to a  
3   temporal limit related to a course of patient care; and

4           a feedback module comparing a time span between each patient status  
5 change for each recorded measure to the stickiness indicator corresponding to the  
6 same type of patient information as the recorded measure being compared.

1           24.     A system according to Claim 12, further comprising:  
2           a feedback module providing automated feedback to the individual patient  
3 when an atrial fibrillation finding is diagnosed.

1           25.     A system according to Claim 24, further comprising:  
2           the feedback module performing an interactive dialogue between the  
3 individual patient and the patient care system regarding the individual patient.

1           26.     An automated patient care system for diagnosing and monitoring  
2 outcomes of atrial fibrillation for remote patient care, comprising:  
3           a medical device regularly recording measures relating to at least one of  
4 monitoring reduced exercise capacity and respiratory distress;  
5           a database maintaining information for an individual patient, comprising  
6 organizing a plurality of monitoring sets in a database, and storing the recorded  
7 measures for the individual patient on a substantially continuous basis into a  
8 monitoring set in the database;  
9           a server evaluating at least one of atrial fibrillation onset, progression,  
10 regression, and status quo, comprising:  
11              a comparison module receiving a diagnosis of atrial fibrillation and  
12 determining on a periodic basis a patient status change in response to the atrial  
13 fibrillation diagnosis by comparing at least one recorded measure from each of the  
14 monitoring sets to at least one other recorded measure with both recorded  
15 measures relating to the same type of patient information; and  
16              an analysis module testing on a periodic basis each patient status  
17 change for an absence, an onset, a progression, a regression, and a status quo of  
18 atrial fibrillation against a predetermined indicator threshold corresponding to the  
19 same type of patient information as the recorded measures which were compared,  
20 the predetermined indicator threshold corresponding to a quantifiable

21 physiological measure of a pathophysiological diagnosis indicative of reduced  
22 exercise capacity and respiratory distress.

1           27. A system for managing a pathophysiological outcome of atrial  
2 fibrillation for remote patient care, comprising:  
3           a database storing a plurality of monitoring sets from a database which  
4 each comprises recorded measures relating to patient information recorded on a  
5 substantially continuous basis;  
6           a server receiving a diagnosis of atrial fibrillation and determining on a  
7 periodic basis the pathophysiological outcome of atrial fibrillation in response to  
8 the atrial fibrillation diagnosis, comprising:  
9           a comparison module comparing at least one recorded measure  
10 from each of the monitoring sets to at least one other recorded measure from  
11 another of the monitoring sets with both recorded measures relating to a same  
12 type of patient information and evaluating on a periodic basis each recorded  
13 measure comparison for an absence, an onset, a progression, a regression, and a  
14 status quo of atrial fibrillation against a predetermined indicator threshold  
15 corresponding to the same type of patient information as the recorded measures  
16 which were compared, the indicator threshold corresponding to a quantifiable  
17 physiological measure of a pathophysiological diagnosis resulting from atrial  
18 fibrillation; and  
19           an analysis module managing the atrial fibrillation outcome by  
20 interventively administering therapy contributing to normal sinus rhythm  
21 restoration and ventricular rate response control.

1           28. A system according to Claim 27, wherein the pathophysiological  
2 outcome comprises a cardiovascular or cardiopulmonary compromise, further  
3 comprising:  
4           a comparison submodule measuring a magnitude of change and a time  
5 span occurrence and classifying a severity of the cardiovascular or  
6 cardiopulmonary compromise according to the magnitude of change and the time  
7 span for each recorded measure comparison; and

8           an analysis submodule generating a therapy regimen based on the severity,  
9 comprising, in decreasing order of severity:  
10           for the cardiovascular or cardiopulmonary compromise with a  
11 highest severity, a submodule administering an aggressive atrial fibrillation  
12 therapy;  
13           for the cardiovascular or cardiopulmonary compromise of second  
14 highest severity, a submodule administering initial anticoagulation management  
15 coupled with selective ventricular rate response control for atrial fibrillation of  
16 long term duration and administering an aggressive atrial fibrillation therapy in  
17 the presence of anticoagulation drug therapy;  
18           for the cardiovascular or cardiopulmonary compromise of third  
19 highest severity, a submodule administering initial monitored anticoagulation  
20 management coupled with selective ventricular rate response control, for atrial  
21 fibrillation of long term duration, administering a moderate atrial fibrillation  
22 therapy coupled with ventricular rate response control, for atrial fibrillation of  
23 long term duration and administering a moderate atrial fibrillation therapy, for  
24 atrial fibrillation in the absence of anticoagulation drug therapy; and  
25           for the cardiovascular or cardiopulmonary compromise of least  
26 severity, a submodule administering initial anticoagulation management coupled  
27 with selective ventricular rate response control and on-going cardiovascular or  
28 cardiopulmonary monitoring, for atrial fibrillation of long term duration,  
29 administering a modest atrial fibrillation therapy, for atrial fibrillation of long  
30 term duration and administering a modest atrial fibrillation therapy, for atrial  
31 fibrillation in the absence of anticoagulation drug therapy.

1           29.     A system according to Claim 27, wherein the pathophysiological  
2 outcome comprises an inappropriate ventricular rate response, further comprising:  
3           a comparison submodule measuring an average ventricular rate and  
4 classifying ventricular rate response according to the average ventricular rate; and  
5           an analysis submodule generating a therapy regimen based on the severity,  
6 comprising:

7                   for overly slow ventricular rate response, a submodule performing  
8 at least one therapy selected from the group comprising increasing ventricular  
9 pacing rate and decreasing antidromotropic drug therapy; and  
10                  for overly rapid ventricular rate response, a submodule performing  
11 at least one therapy selected from the group comprising applying electrical  
12 therapy and administering initial drug therapy to decrease atrioventricular node  
13 conduction.

1                 30. A system according to Claim 27, wherein the pathophysiological  
2 outcome comprises a pathophysiological condition requiring anticoagulation drug  
3 therapy, further comprising:

4                   a comparison submodule determining a duration for atrial fibrillation and  
5 anticoagulation drug therapy status; and  
6                   an analysis submodule administering anticoagulation drug therapy for  
7 atrial fibrillation of long term duration in the absence of a contraindication of  
8 anticoagulation drug therapy or inadequacy thereof.

1                 31. A system according to Claim 27, wherein the pathophysiological  
2 outcome comprises palpitations or symptoms, further comprising:

3                   a comparison submodule classifying palpitations or symptoms according  
4 to disabling effect to the patient; and  
5                   an analysis submodule generating a therapy regimen based on the  
6 classification, comprising:

7                   for disabling palpitations or symptoms, a submodule administering  
8 a moderate atrial fibrillation therapy for atrial fibrillation; and  
9                   for non-disabling palpitations or symptoms, a submodule  
10 administering a modest atrial fibrillation therapy for atrial fibrillation.